

HYDROGEN PEROXIDE- hydrogen peroxide solution
Vi-Jon, LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Drug Facts Mountain Falls 871.001-871AA

Active ingredient

Hydrogen peroxide (stabilized) 3%

Purpose

First Aid Antiseptic

Oral debriding agent

Uses

- first aid to help prevent the risk of infection in minor cuts, scrapes and burns
- aids in the removal of phlegm, mucus, or other secretions associated with occasional sore mouth

Warnings

For external use only

Do not use

- in the eyes or apply over large areas of the the body
- longer than one week

Ask a doctor before use if you have

deep or puncture wounds, animal bites or serious burns

Stop use and ask a doctor if

- the condition persists or gets worse
- sore mouth symptoms do not improve in 7 days
- irritation, pain or redness persists or worsens
- swelling, rash, or fever develops

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away.

Directions

For First aid:

- clean the affected area
- spray a small amount of product on the affected area 1 to 3 times a day
- may be covered with a sterile bandage
- if bandaged, let dry first

Oral debriding agent: adults, children over 2 years of age:

- mix with an equal amount of water
- swish around in the mouth over the affected area for at least 1 minute, then spit out
- use up to 4 times daily after meals and at bedtime
- children under 12 years of age should be supervised in the use
- children 2 years of age: consult a dentist, doctor

Other information

keep tightly closed and at controlled room temperature. Do not shake bottle. Hold away from face when opening.

Inactive ingredients

purified water
Manufactured by: Vi-Jon, LLC., St. Louis, MO 63114
Questions or Comments? 1-888-593-0593
871.000/871AA

Swan Hydrogen Peroxide Topical Solution USP
First Aid Antiseptic/Oral Debriding Agent
For treatment of minor cuts & abrasions
For use as a gargle or rinse
Square bottle uses less plastic than a similarly sized round bottle. Recyclable (if available in your area)
SEALED WITH PRINTED NECKBAND FOR YOUR PROTECTION
16 FL OZ (1 PT) 473 mL

principal display panel

Do not use if printed seal under cap is broken or missing
mountain falls
for treatment of minor cuts and abrasions
3% U.S.P. hydrogen peroxide topical solution USP
first aid antiseptic
oral debriding agent
Made in the USA with US and foreign parts
32 FL OZ (1 QT) 946 mL

HYDROGEN PEROXIDE			
hydrogen peroxide solution			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0869-0871
Route of Administration	TOPICAL		
Active Ingredient/Active Moiety			
Ingredient Name		Basis of Strength	Strength
HYDROGEN PEROXIDE (UNII: BBX060AN9V) (HYDROGEN PEROXIDE - UNII:BBX060AN9V)		HYDROGEN PEROXIDE	30 mg in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0869-0871-72	295 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	07/09/2017	
2	NDC:0869-0871-43	473 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/09/2017	
3	NDC:0869-0871-45	946 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/09/2017	
4	NDC:0869-0871-18	118 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	07/09/2017	
5	NDC:0869-0871-99	237 mL in 1 BOTTLE, SPRAY; Type 0: Not a Combination Product	07/09/2017	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part333A	07/09/2017	

Labeler - Vi-Jon, LLC (790752542)

Registrant - Vi-Jon, LLC (790752542)

Establishment			
Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		790752542	manufacture(0869-0871)

Establishment			
Name	Address	ID/FEI	Business Operations
Vi-Jon, LLC		088520668	manufacture(0869-0871)